

K053248

DEC 1 2005

## ELECTROMED, INC.

502 Sixth Avenue N.W.  
New Prague, MN 56071  
Phone: 952-758-9299 Fax: 952-758-1941

### 510(k) SUMMARY

Date: October 15, 2005

Submitter: Chet Sievert  
Regulatory Representative  
Electromed, Inc.  
502 Sixth Avenue N.W.  
New Prague, MN 56071  
Phone: 952.758.9299  
Fax: 952.758.1941

Contact person: Chet Sievert

Name of Device: Electromed SmartVest® Airway Clearance System,  
Model TL

Classification: Powered Percussor, Class II

Predicate Device: MedPulse® Respiratory Vest System, Model 2000 ez  
510(K) number: K040367

Description of Device:

The proposed SmartVest® Airway Clearance System, Model TL is designed to deliver high-frequency chest wall oscillation to promote airway clearance and improve bronchial drainage. The SmartVest® System is indicated when external chest manipulation is the physician's treatment of choice to enhance mucus transport. The primary components of the SmartVest® System include an Air-Pulse Generator, an Inflatable Vest and Vest/Generator Connector Hose. The Air-Pulse Generator produces oscillating pressurized air-pulses that are delivered to the Inflatable Vest by the Vest/Generator Hose. The air-pulses produced by the Generator cause the Vest to rapidly inflate and deflate against the external chest wall of a patient to promote airway clearance by creating high-frequency chest wall oscillation (HFCWO) resulting in mobilization of bronchial secretions.

Intended Use:

The Electromed SmartVest® Airway Clearance System, Model TL is designed to deliver high-frequency chest wall oscillation to promote airway clearance and improve bronchial drainage. The SmartVest® System is indicated when external chest manipulation is the physician's treatment of choice to enhance mucus transport.

### 510(k) SUMMARY (continued)

#### Comparison of Technological Characteristics:

The proposed SmartVest® Airway Clearance System, Model TL has the same technological characteristics and principles of operation as Electromed's previously cleared Medpulse® Respiratory Vest System Model 2000 ez (K040367). The proposed SmartVest® System will continue to use the same method of generating pressurized air-pulses as the predicate, i.e., by dual acting pneumatic diaphragm technology. The user of the proposed System will continue to be able to adjust air pulse frequency and pressure amplitude in the same manner as the predicate system.

The first reason for this submission is due to a component change to the Air-Pulse Generator's pneumatic diaphragm. The proposed change reduces the size of the pneumatic diaphragm and therefore the Generator's over-all size. The second proposed change is to add several features to the Generator Control Panel that required software changes. These features allow the user to view the Control Panel in multiple directions during use and a Sleep Mode that automatically shuts off the device if left unattended.

A Vest that is dedicated for hospital use and additional Vest sizes were also added to the product line. In addition, a softer vest lining is proposed to accommodate user comfort.

#### Performance Testing:

The proposed SmartVest® Airway Clearance System, Model TL was tested and compared to the predicate Medpulse® Respiratory Vest System Model 2000 ez (K040367). Testing included measuring the pressure imparted to the chest wall of both the proposed and predicate systems. Functional performance and electrical safety tests were performed that demonstrated no change in output performance or safety issues to result from the changes proposed.

#### Substantial Equivalence:

The proposed SmartVest® Airway Clearance System, Model TL has the identical indications and intended use, technological characteristics and principles of operation as the predicate device. Functional performance and electrical safety testing have demonstrated no changes in safety or effectiveness. Thus, the proposed SmartVest® Airway Clearance System, Model TL is substantially equivalent to the proposed Medpulse® Respiratory Vest System Model 2000 ez (K040367).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 1 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Electromed, Incorporated  
C/O Mr. Neil Devine  
Responsible Third Party Official  
Intertek Testing Services  
70 Codman Hill Road  
Boxborough, Massachusetts 01719

Re: K053248

Trade/Device Name: Electromed Smartvest<sup>®</sup> Airway Clearance System, Model TL  
Regulation Number: 21 CFR 868.5665  
Regulation Name: Powered Percussor  
Regulatory Class: II  
Product Code: BYI  
Dated: October 18, 2005  
Received: November 21, 2005

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

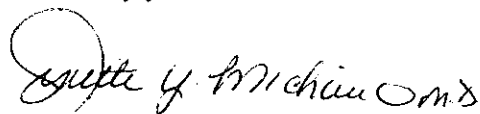
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin, Ph.D.", with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

VII. Indications for Use Statement

**Indications for Use**

510(k) Number (if known): \_\_\_\_\_

Device Name: ELECTROMED SMARTVEST® AIRWAY CLEARANCE SYSTEM,  
MODEL TL

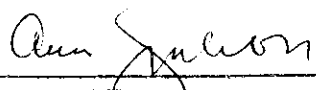
Indications For Use:

The Electromed SmartVest® Airway Clearance System, Model TL is designed to deliver high-frequency chest wall oscillation to promote airway clearance and improve bronchial drainage. The SmartVest® System is indicated when external chest manipulation is the physician's treatment of choice to enhance mucus transport.

Prescription Use   X   AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
Division Sign-Off  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices  
510(k) Number:   K053248